

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 701019 CLIENT REF. NO. Tak-201493 U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/582,602
INTERNATIONAL APPLICATION NO. PCT/JP2004/018479	INTERNATIONAL FILING DATE 10 December 2004 (10.12.2004)	PRIORITY DATE CLAIMED 11 December 2003 (11.12.2003)
TITLE OF INVENTION α-AMINO ACID DERIVATIVES AND USE THEREOF AS MEDICINES		
APPLICANT(S) FOR DO/EO/US AKAHOSHI et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 USC 371 and 37 CFR 1.491. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 USC 371 and 37 CFR 1.491. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 USC 371(f)). 4. <input type="checkbox"/> The US has been elected (PCT Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 USC 371(c)(2)) a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 USC 371(c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has previously been submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 USC 371(c)(3)) a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 USC 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 USC 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 USC 371(c)(5)). 11. Nucleotide and/or Amino Acid Sequence Submission a. <input type="checkbox"/> Computer Readable Form (CRF) b. Specification Sequence Listing on: i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or ii. <input type="checkbox"/> Paper Copy c. <input type="checkbox"/> Statement verifying identity of above copies		
Items 12 to 20 below concern other document(s) or information included:		
12. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of References (except for U.S. patents and applications) 13. <input type="checkbox"/> An assignment for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 14. <input type="checkbox"/> A FIRST preliminary amendment. 15. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 16. <input type="checkbox"/> A substitute specification. 17. <input type="checkbox"/> A change of power of attorney and/or address letter. 18. <input type="checkbox"/> Application Data Sheet Under 37 CFR 1.76 19. <input checked="" type="checkbox"/> Return Receipt Postcard 20. <input type="checkbox"/> Other items or information:		

SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

U.S. APPLICATION NO. (if known, see 37 CFR 1.6) 10/582,602		INTERNATIONAL APPLICATION NO. PCT/JP2004/018479		ATTORNEY DOCKET NO. 701019		CLIENT REF. NO. Tak-201493	
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The following fees are submitted:

	CALCULATIONS	PTO USE ONLY																
21. <input type="checkbox"/> Basic national fee \$300	\$																	
22. <input type="checkbox"/> Examination Fee																		
If international preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) \$ 0	\$																	
All other situations \$200																		
23. <input type="checkbox"/> Search Fee																		
USPTO was ISA \$100	\$																	
Search report provided to USPTO by other entity \$400																		
All other situations \$500																		
TOTAL OF 21, 22 AND 23 =	\$																	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.	\$																	
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:20%;">Total Sheets</th> <th style="width:20%;">Extra Sheets</th> <th style="width:40%;">Number of each additional 50 or fraction thereof (round up to a whole number)</th> <th style="width:20%;">RATE</th> </tr> <tr> <td style="text-align: center;">- 100 =</td> <td style="text-align: center;">/ 50 =</td> <td></td> <td style="text-align: center;">x \$250</td> </tr> </table>	Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	- 100 =	/ 50 =		x \$250	\$									
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE															
- 100 =	/ 50 =		x \$250															
<input type="checkbox"/> Surcharge of \$130 for furnishing the National fee or oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).	\$0.00																	
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:20%;">CLAIMS</th> <th style="width:20%;">NUMBER FILED</th> <th style="width:40%;">NUMBER EXTRA</th> <th style="width:20%;">RATE</th> </tr> <tr> <td>Total Claims</td> <td style="text-align: center;">- 20 =</td> <td></td> <td style="text-align: center;">x \$ 50</td> </tr> <tr> <td>Independent Claims</td> <td style="text-align: center;">- 3 =</td> <td></td> <td style="text-align: center;">x \$200</td> </tr> <tr> <td colspan="3">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td style="text-align: center;">+ \$360</td> </tr> </table>	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total Claims	- 20 =		x \$ 50	Independent Claims	- 3 =		x \$200	MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE															
Total Claims	- 20 =		x \$ 50															
Independent Claims	- 3 =		x \$200															
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360															
TOTAL OF ABOVE CALCULATIONS =																		
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.	\$ ()																	
SUBTOTAL =	\$																	
<input type="checkbox"/> Processing fee of \$130 for furnishing English Translation later than 30 months from the earliest claimed priority date.	\$																	
TOTAL NATIONAL FEE =	\$0.00																	
<input type="checkbox"/> Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property.	\$																	
TOTAL FEES ENCLOSED =	\$0.00																	
	Amount to be: refunded	\$																
	Amount to be: charged:	\$																

a. ☐ No fee is believed to be due.


b. ☒ Please charge Deposit Account No. 12-1216 the total fee indicated above.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 12-1216. A duplicate copy of this sheet is enclosed.


NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO CUSTOMER NO. 23460:

23460


 John Kirk, Jr., Registration No. 30,763
 LEYDIG, VOIT & MAYER, LTD
 Two Prudential Plaza, Suite 4900
 180 North Stetson Avenue
 Chicago, Illinois 60601-6780
 (312) 616-5600 (telephone)
 (312) 616-5700 (facsimile)

Date: September 1, 2006

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/582,602	INTERNATIONAL APPLICATION NO. PCT/JP2004/018479	ATTORNEY DOCKET NO. 701019	CLIENT REF. NO. Tak-201493
EV 708754350 US "Express Mail" Mailing Number		September 1, 2006 Date of Deposit	
<p>I hereby certify that this transmittal document with respect to the U.S. national phase of the above-referenced International Patent Application, including all of the items listed thereon as enclosures, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p>			
John Kilyk, Jr. Typed or Printed Name of Person Making Deposit		 Signature of Person Making Deposit	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/582,602

Applicant: Akahoshi et al.

Filed: June 9, 2006

TC/AU: Unassigned

Examiner: Unassigned

Docket No.: 701019 (Client Reference No. 201493)

Customer No.: 23460

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date

of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
- ☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or*
- ☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

Copies of the References

- ☐ Copies of all of the references listed on the enclosed Form 1449 are enclosed herewith.
- ☒ Copies of U.S. patents and patent applications that are listed on the accompanying Form 1449 are not enclosed herewith. Copies of other references identified on the accompanying Form 1449 are enclosed herewith.
- ☒ Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- ☒ A copy of the foreign search report is enclosed herewith.
- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not

submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		STATUS (check one)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

Statement under 37 CFR 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Fees

- ☒ No fee is owed by the applicant(s).
☐ Charge Deposit Account No. 12-1216 in the amount of **\$180.00** (37 CFR 1.17(p)).
(A duplicate copy of this communication is enclosed for that purpose.)

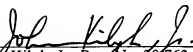
In re Appln. of Akahoshi et al.
Application No. 10/582,602

Authorization to Charge Additional Fees

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

Instructions as to Overpayment

- ☒ Credit Account No. 12-1216.
☐ Refund



John Kilyk, Jr., Reg. No. 30,763
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: September 1, 2006



Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/582,602
Filing Date	June 9, 2006
First Named Inventor	AKAHOSHI, Fumihiko
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	701019
Client Reference No.	201493

Sheet 1 of 1

U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
		Application or Patent Number	Kind Code			
	AA	2003/0134802	A1	Demuth et al.	Jul. 17, 2003	
	AB	2004/0063935	A1	Yasuda et al.	Apr. 1, 2004	
	AC	2004/0106656	A1	Ashton et al.	Jun. 3, 2004	
	AD	2004/0229926	A1	Yasuda et al.	Nov. 18, 2004	
	AE	2005/0054678	A1	Yasuda et al.	Mar. 10, 2005	
	AF	2005/0203030	A1	Demuth et al.	Sep. 15, 2005	
	AG	6,548,481	B1	Demuth et al.	Apr. 15, 2003	
	AH	6,849,622	B2	Yasuda et al.	Feb. 1, 2005	
	AI	7,026,316	B2	Ashton et al.	Apr. 11, 2006	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	AJ	WO	99/61431	A1	Probiolab Gesellschaft für Arzneimittel-forschung MBH	Dec. 2, 1999		x**
	AK	WO	02/30801	A1	Tenabo Seiyaku Co., Ltd.	Apr. 18, 2002		x**
	AL	WO	02/076450	A1	Merck & Co., Inc.	Oct. 3, 2002		
	AM	JP	2004-244412	A	Kotobuki Seiyaku KK	Sept. 2, 2004		x**

OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
	AN	HEYMANN et al., <i>FEBS Letters</i> , 91(2): 360-364 (July 1978)		
	AO	SCHÖN et al., <i>Biomed. Biochim. Acta</i> , 44(2): K9-K15 (1985)		
	AP	JOHNSON et al., <i>The Journal of Cell Biology</i> , 121(6): 1423-1432 (1993)		
	AQ	CALLEBAUT et al., <i>Science</i> , 262: 2045-2050 (December 24, 1993)		
	AR	DEACON et al., <i>Journal of Clinical Endocrinology and Metabolism</i> , 80(3): 952-957 (1995)		
	AS	DEACON et al., <i>American Journal of Physiology</i> , 271: E458-E464 (1996)		
	AT	KNUDSEN et al., <i>European Journal of Pharmacology</i> , 318: 429-435 (1996)		
	AU	WIEDEMAN et al., <i>Current Opinion in Investigational Drugs</i> , 4(4): 412-420 (2003)		
	AV	CALDWELL et al., <i>Bioorganic & Medicinal Chemistry Letters</i> , 14: 1265-1268 (2004)		
	AW	PARMEE et al., <i>Bioorganic & Medicinal Chemistry Letters</i> , 14: 43-46 (2004)		

Examiner Signature	/Noble Jarrell/ (04/09/2008)	Date Considered	
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* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

* An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.J./ (04/09/2008)